

TSS/IRB SAFETY REVIEW

February 14, 1984

TO: PM 15

SUBJECT: 000602-00301  
Purina Livestock Residual  
Insecticide  
Ralston Purina Co.  
St. Louis, MO 63164

IN TSS: 02-07-84  
AC: 305  
DUE: 03-02-84  
ACCN: 252343  
RN: 114940  
OLTS:

FORMULATION: Tetrachlorvinphos(rabon).....24.00%  
Phenol.....  
[REDACTED]

BACKGROUND

\*Inert ingredient information may be entitled to confidential treatment\*

This is a submission of data for a registered product. The registrant has submitted 5 acute toxicology studies, and wishes to add a sticker to the label reflecting new hazards via the ocular route of exposure. (Sig. Word DANGER and Tox. I statements).

USES

Topical application after dilution to beef cattle, swine, and poultry.

SUBMITTED DATA

1. Acute Oral LD<sub>50</sub>. SR Project 21, Exp. 279. Health Industries Research Center. 6 M and 6 F S.D. rats per dose. Animals dosed by gavage at 440, 879, 3516, and 7032 mg/kg. LD<sub>50</sub> for males reported as 3593(2523-7146) and overall as 2381(1786-3362) but the females were not calculated due to unusual results. The actual group and individual mortalities were not reported. The individual necropsy data were not submitted.

Invalid Data. Actual group and individual results and necropsies must be submitted.

2. Acute Dermal LD<sub>50</sub>. Hazleton Raltech, Madison WI. RT Lab 800081. 10 albino rabbits, individually housed. All sites clipped but not abraded. 24 hour exposure to 2g/kg. 14 day observation period. No mortality. Severe skin irritation noted. Individual necropsies unreported, but summary indicates most were normal.

Core Minimum Data

TOXICITY CATEGORY III

3. Primary Eye Irritation. 6 NZ white rabbits. 0.1 ml per eye. Flourescein scan used for evaluations. All eyes unwashed. 7 day observation period. Results:

Corneal Opacity- 6/6 had not cleared in the 7 day period

Iritis- 4/6 had not cleared at day 7.

Conjunctivae- 6/6 still had irritation at day 7

Core Minimum Data

TOXICITY CATEGORY I

4. Primary Dermal Irritation. 6 white albino rabbits, were tested but no results were reported.

Invalid Data

5. Acute Inhalation Toxicity. Hazleton Labs. Vienna, VA 22180 Project No. 2200-105. 5 M and 5 F S.D. rats. 4 hour exposure to a gravimetric concentration of 3.61 mg/L (Nominal 8.14) as determined by membrane and charcoal tube filters. Particle size MMD 2.19 u as determined by cascade impactor. No mortality occurred. Signs during exposure included languidity and rhinorrhea. Necropsies normal except for the lung of one female which did not inflate and the kidneys of one female which were red and dilated.

Core Minimum Data

TOXICITY CATEGORY III

SUMMARY OF THE SUBMITTED DATA

<u>Study</u>	<u>Result</u>	<u>Tox. Cat.</u>
Acute Oral LD <sub>50</sub>	Invalid Data	-
Acute Dermal LD <sub>50</sub>	$\geq$ 2000 mg/kg	III
Pri. Dermal Irr.	Invalid Data	-
Pri. Eye Irr.	Irreversible Damage	I
Acute Inhalation	$\geq$ 3.61 mg/L	III

CONCLUSIONS

1. The acute dermal, primary eye irritation, and inhalation studies are acceptable.
2. The actual data for the acute oral and skin irritation data were not submitted. These must be submitted to permit review of the potential hazards from these routes of exposure.
3. The sticker concept is acceptable until the label is revised. *no - must comply with PB-Adiro 43-4 Aisd*
4. Complete label revision should be delayed until the results of the acute oral and skin irritation studies are submitted and reviewed. Skin irritation was noted in the dermal LD<sub>50</sub> study, and changes in the final labelling for this route of exposure would appear likely.

Phil Hutton  
TSS/IRB